Lopinavir-RTV + Lamivudine vs. Lopinavir-RTV + 2NRTIs

GARDEL Trial

Lopinavir-RTV + Lamivudine versus Lopinavir-RTV + 2NRTIs
GARDEL: Study Design

Study Design: GARDEL

- **Background**: Randomized, phase 3, open-label, non-inferiority trial comparing the efficacy of dual therapy with lopinavir-ritonavir plus lamivudine versus standard lopinavir-ritonavir plus 2NRTIs in treatment-naïve patients with HIV infection
- **Inclusion Criteria (n = 426)**
  - Age ≥18
  - Antiretroviral-naïve
  - HIV RNA ≥1000 copies/mL
- **Treatment Arms**
  - LPV/r (400/100 mg) BID + 3TC 150 mg BID
  - LPV/r (400/100 mg) BID + (3TC or FTC) + 1 NRTI

Dual Therapy
LPV-RTV + 3TC
(n=217)

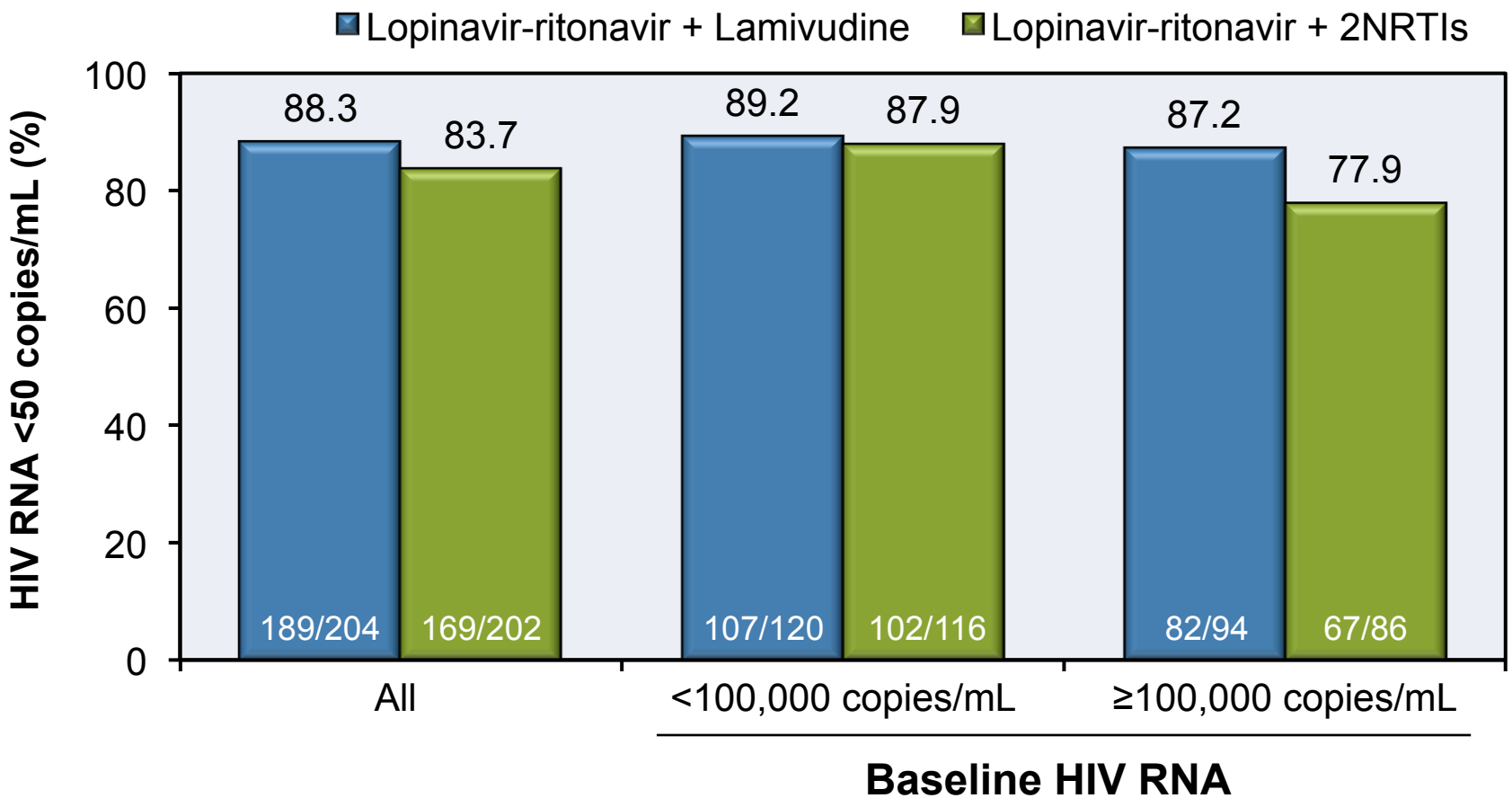
Triple Therapy
LPV-RTV + 2 NRTIs
(n = 209)

GARDEL = **G**lobal **A**nti**R**etroviral **D**esign **E**ncompassing **L**opinavir/r and Lamivudine vs LPV/r based standard therapy

Source: Cahn P, et al. Lancet Infect Dis. 2014;14:572-80.

Lopinavir-RTV + Lamivudine versus Lopinavir-RTV + 2NRTIs
GARDEL: Results

Week 48: Virologic Response (ITT, exposed, snapshot)



Source: Cahn P, et al. Lancet Infect Dis. 2014;14:572-80.

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GARDEL: Results

Clinical Adverse Events and Laboratory Abnormalities		
Adverse Event	**LPV-RTV + 3TC** (n = 212)	**LPV-RTV + 2NRTIs** (n = 202)
Total number of grade 2-3 AEs (possibly or probably drug related)	30%	44%
Total number of patients with grade 2-3 AEs (possibly or probably drug related)	20%	24%
Serious AEs (possibly or probably drug related)	<1%	0%
Safety events leading to discontinuation	1%	5%

Source: Cahn P, et al. Lancet Infect Dis. 2014;14:572-80.

Lopinavir-RTV + Lamivudine versus Lopinavir-RTV + 2NRTIs
GARDEL: Interpretation

Interpretation: “Dual therapy with lopinavir and ritonavir plus lamivudine regimen warrants further clinical research and consideration as a potential therapeutic option for antiretroviral-therapy-naive patients.”

Source: Cahn P, et al. Lancet Infect Dis. 2014;14:572-80.

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The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.

National HIV Curriculum

AETC AIDS Education & Training Center Program
National Coordinating Resource Center